FEDESA position
on VICH GL9: Good Clinical Practice

FEDESA believes that this is a clear and concise document, which will in our opinion be useful for further ensuring the quality of clinical trials and data integrity.

A couple of **specific comments** are listed as follows:

Paragraphs 1.15 and 2.7
Comment: The proposed definition of the Investigational Veterinary Product in Par. 1.15 includes animal feeds which contain test substances. Further, Par. 2.7 indicates that investigational veterinary products should be prepared, handled and stored under GMP conditions. While surely, medicated feeds must be prepared, handled and stored taking the appropriate precautionary measures. Further, appropriate labeling procedures should be followed and recordings should be made of the manufacturing process, test article use and quantities of feed produced. However, full GMP practices may not always be applicable for local commercial feed mills in which these medicated feeds are manufactured.
Proposal: Therefore, animal feeds should be removed from the definition of investigational veterinary product.

Paragraph 2.7
Proposal: Insert as a first sentence: "While the development studies on the galenic form are not normally within the control of GMP inspections, they should nevertheless take account of such principles where appropriate. Therefore whenever possible...".
Comment: Cited from Note for guidance: Development Pharmaceutics for veterinary medicinal products while the development.

Paragraph 2.8 - 3rd sentence
Comment: The sponsor can not be responsible for QA. This has to an independant role.
Proposal: The sentence should be rephrased: "The sponsor would be the party responsible for ensuring the QA audit".

Paragraph 3.1.4
Comment: Currently, the text indicates that the investigator is employed by the sponsor. However, very often, the investigator will NOT be a sponsor's employee.
Proposal: We therefore suggest to edit the wording to "The investigator is appointed/contracted by the sponsor." (or equivalent wording).

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Paragraph 3.2.30 and 8.1.2
Comment: The period of time for storage of study documentation should be fixed for all countries.
Proposal: We suggest 10 years from the date of issue of the Final Study Report.

Paragraph 3.2.31
Comment: An authenticated copy of the forwarded information should be retained by the investigator. This means that the investigator needs to have an own archive. Since investigators are usually practising vets without specific archive facilities this seems to be not very easy to fulfill. Should archiving by the investigator be mandatory?
Proposal: Change last sentence: "When all part of the study documentation is forwarded to the sponsor, it is **recommended** an authenticated copy of the forwarded information should be retained by the investigator.

Paragraph 4.2.11
Comment: This paragraph states that the sponsor should "Ensure the proper final and safe disposal of all study animals and any edible products derived from them." In our opinion, it will be sufficient to ensure the safe disposal.
Proposal: To delete: "... final and...".

Paragraph 4.2.16
Proposal: In place of "Implement quality audit...", the text should read "Organise quality audit...".

Paragraph 7.2.4
We do not see the necessity to state who of the authors contributed to which part of the report.

Paragraphs 7.3.6.4 and 7.3.6.5.5
Comment: These paragraphs state that a complete description of the disposal of study animals and their edible products as well as a full inventory of the test material should be included in the study report. In our opinion, it will be sufficient to ensure that this information is available in the trial master file archive. However, we do not believe it will be necessary to include this information in the study report.
Proposal: To transfer these two paragraphs to Section 8 of the guideline ("Study Documentation").

Paragraph 8.1.2
Comment: Auditing should not be obligatory, but could or might be.
Proposal: The 3rd sentence should be rephrased: "Study documentation might be audited by..."